

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: KEI ROGER AOKI et al.

Examiner: GUPTA, Anish

Serial No.: 10/726,904

Group Art Unit: 1654

Filed: December 2, 2003

Confirmation No.: 4172

For: USE OF THE NEUROTOXIC  
COMPONENT OF A  
BOTULINUM TOXIN FOR  
TREATING A SPASTIC MUSCLE

Irvine, California

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant's provide with regard to the patent application entitled USE OF THE NEUROTOXIC COMPONENT OF A BOTULINUM TOXIN FOR TREATING A SPASTIC MUSCLE, filed herewith one copy of documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

/STEPHEN DONOVAN/

Date: April 12, 2007

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### LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 16952-CON1-CIP3 (BOT)	SERIAL NO.: 10/726,904
APPLICANT: AOKI et al.	TITLE: USE OF THE NEUROTOXIC COMPONENT OF A BOTULINUM TOXIN FOR TREATING A SPASTIC MUSCLE
FILING DATE: DECEMEBER 2, 2003	GROUP: 1654

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	2,373,454	04/10/1945	Bunney, et al.	167	68	07/09/1943
	AB	2,719,102	09/27/1955	Baldwin	167	68	10/28/1949
	AC	3,132,995	05/12/1964	Berger, et al.	167	68	10/20/1961
	AD	4,832,936	05/23/1989	Holter, et al.	423	555	09/21/1987
	AE	4,932,936	06/12/1990	Dykstra, et al.	604	51	01/29/1988
	AF	5,053,005	10/01/1991	Borodic	604	51	04/21/1989
	AG	5,055,302	10/08/1991	Laties, et al.	424	427	02/22/1990
	AH	5,056,291	10/15/1991	Leung, et al.	52	637	10/19/1989
	AI	5,183,462	02/02/1993	Borodic	604	51	08/21/1990
	AJ	5,298,019	03/29/1994	Borodic	604	51	01/13/1993
	AK	5,401,243	03/28/1995	Borodic	604	51	04/12/1993
	AL	5,437,291	08/01/1995	Pasricha, et al.	128	898	08/26/1993
	AM	5,562,907	10/08/1996	Arnon	424	236.1	06/06/1994
	AN	5,766,605	06/16/1998	Sanders, et al.	424	239.1	04/15/1994
	AO	6,290,961	09/18/2001	Aoki, et al.	424	184.1	01/24/2000
	AP	2002/0102275	08/01/2002	Graham	424	247.1	03/22/2002

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA	WO 94/28923	12/22/1994	PCT	A61K	37/02	Y
	BB	WO 94/00481	01/06/1994	PCT	A61K	37/02	Y
	BC	WO 95/28171	10/26/1995	PCT	A61K	38/16	Y

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	"Porton Refocuses on Pharmaceuticals" <u>Scrip</u> , No. 1871, 10 (Vol. 9, No. 1993).
	CB	Med. Ad. News Staff, "Athena Makes a Wise Move" <u>Medical Advertising News</u> ; p. 4, (Nov. 1992).
	CC	U.S. Food and Drug Administration, List of Orphan Designations and Approvals; pp. 1 and 42-46, (computer search printout January 18, 2000).
	CD	Adenis, J.P., et al., "Traitement des Spasmes Faciaux Par La Toxine Botulique A" <u>J.Fr. Ophtalmal.</u> , Vol. 13, No. 5; pp. 259-264, (1990).
	CE	Ambache, J. <u>Physiol.</u> , Vol. 108; pp. 127-141, (1949).
	CF	Ambache, N., "A Further Survey of the Action of Clostridium Botulinum Toxin Upon Different Types of Autonomic Nerve Fibre" <u>J. Physiol.</u> , Vol. 113; pp. 1-17, (1951).

EXAMINER \_\_\_\_\_

DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CG	Brin, Arch. De Neurobiol, Vol. 54, Supl. 3; pp. 7-23, (1991).
CH	Das, T.K. et al., "Effect of treatment with Botulinum toxin on spasticity" <u>Postgraduate Medical Journal</u> , Vol. 65; pp. 208-210, (1989).
CI	Habermann, "Foreword" <u>Botulinum and Tetanus Neurotoxins</u> , published by Plenum Press; pp. v – ix, (1993).
CJ	Dykstra, D., et al., "Treatment of Detrusor-Sphincter Dyssynergia with Botulinum A Toxin: A Double-Blind Study" <u>Arch. Phys. Med. Rehabil.</u> , Vol. 71; pp. 24-26, (January 1990).
CK	Elston, et al., "Paralytic strabismus: the role of botulinum toxin" <u>Br. J. Ophthalmol.</u> , Vol. 69(12); pp. 891-896, (December 1985), Abstract only.
CL	Foster, K.A., "New Wrinkle On Pain Relief: Re-Engineering Clostridial Neurotoxins for Analgesics" <u>Drug Discovery Today</u> , Vol. 10, No. 8; pp. 563-569, (April 2005).
CM	Greene, Paul, et al., "Response to Botulinum Toxin F in Seronegative Botulinum Toxin A-Resistant Patients" <u>Movement Disorders</u> , Vol. 11, No.2; pp. 181-184, (March 1996).
CN	Greene, et al., "Development of Antibodies to Botulinum Toxin Type A in Patients with Torticollis Treated with Injections of Botulinum Toxin Type A" <u>Botulinum and Tetanus Neurotoxins</u> , Plenum Press; pp. 651-654, (1993).
CO	Hambleton, P. "Clostridium Botulinum Toxins: a general review of involvement in disease, structure, mode of action and preparation for clinical use" <u>J. Neurol.</u> , Vol. 239, No. 1; pp. 16-20, (1992).
CP	Harper, K.E., et al., "Frey's Syndrome" <u>International Journal of Dermatology</u> , Vol. 25, No. 8; pp. 524-526, (October 1986).
CQ	Hatheway, C.L., "Bacterial Sources of Clostridial Neurotoxins" <u>Botulinum Neurotoxin and Tetanus Toxin Academic Press</u> , pp. 4-24, (1989).
CR	Jenzer, et al., <u>Schweiz. Med. WSCHR.</u> , Vol. 104; pp. 685-693, with English translation.
CS	Khalafalla, et al., "Botulinum Toxin and Sweating" <u>J. Neurology, Neurosurgery and Psychiatry</u> , Vol. 57; pp. 1437-1438, (1994).
CT	Konstazer, A., et al., "Lokale Injektionsbehandlung mit Botulinum-Toxin A bei schwerer Arm-und Beinspastik" <u>Der Nervenarzt</u> , Vol. 64(8); pp. 517-523, (August 1993).
CU	Laccourreye, et al., "Treatment of Frey's Syndrome in Topical 2% Diphemanil Methylsulfate (Prantal): A Double-Blind Evaluation of 15 Patients" <u>Laryngoscope</u> , Vol. 100; pp. 651-653, (1990).
CV	Ludlow, et al., "Therapeutic Uses of Type F Botulinum Toxin" <u>Letter to New England Journal of Medicine</u> , Vol. 326, No. 5; pp. 349-350, (January 1992).
CW	Memin, et al., "Traitement de la Spasticité par la Toxine Botulique" <u>Rev. Neurol.</u> , Vol. 148(3); pp. 212-214, (1992).
CX	Montecucco, C., et al., "Botulinum Neurotoxins: Mechanism of Action and Therapeutic Applications," <u>Mol. Med. Today</u> , Vol. 2, No. 10; pp. 418-424, (October 1996).
CY	Moyer, E.D., et al., "Effects of Intramuscular Injection of Botulinum Toxin Type B in Nonhuman Primates" <u>Botulinum and Tetanus Neurotoxins-Neurotransmission and Biomedical Aspects</u> , Bibhuti R. Dasgupta, Editor; Plenum Press, (1993).
CZ	Moyer, E., et al. "Botulinum Toxin Type B: Experimental and Clinical Experience" <u>Therapy with</u>

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		<u>Botulinum Toxin</u> , Jankovic J. and Hallett, M., ed., Dekker Publishers: New York, NY; pp. 71-85, (February 1994).
	CAA	Poungvarne, et al., <u>J. Med. Assoc. Thai.</u> , Vol. 75(4); pp. 199-203, (April 1992).
	CBB	Price, J., et al., "A Comparative-Study of Tear Secretion in Blepharospasm and Hemifacial Spasm Patients Treated with Botulinum Toxin" <u>Journal of Clinical Neuro-Ophthalmology</u> , Vol. 13, No. 1; pp. 67-71, (March 1993), Abstract only.
	CCC	Ransom, G.M., et al., "Enzyme-Linked Immunosorbent Assays (ELISAs) to Detect Botulinum Toxins Using High Titer Rabbit Anti-Sera" <u>Botulinum and Tetanus Neurotoxins</u> , Plenum Press; pp. 449-462, (1993).
	CDD	Ruusuvaara, P and Setala, K., "Long-term Treatment of Involuntary Facial Spasms Using Botulinum Toxin" <u>Acta Ophthal.</u> , Vol. 68; pp. 331-338, (1990).
	CEE	Saga, T., et al., "Secretion of Tears in Patients with Hemifacial Spasm" <u>Jpn. J. Ophthalmol.</u> , Vol. 34; pp. 30-35, (1990).
	CFE	Schurch, B., et al., "Effets de la Toxine Botulinique A sur le sphincter strié périurétral des vessies neurogènes" <u>Journal d'Urologie</u> , Vol. 96(7); pp. 375-380, (1990).
	CGG	Scott, Alan B., et al., "Systemic Toxicity of Botulinum Toxin by Intramuscular Injection in the Monkey", <u>Movement Disorders</u> , Vol. 3, No. 4; pp. 333-335, (1988).
	CHH	Scott, Alan B., "A Clinical Preface" <u>Botulinum and Tetanus Neurotoxins</u> , Plenum Press; pp. 557-558, (1993).
	CII	Tang-Liu, D., et al., "Intramuscular Injection of <sup>125</sup> I-botulinum Neurotoxin-Complex Versus <sup>125</sup> I-botulinum-free Neurotoxin: Time Course of Tissue Distribution" <u>Toxicon</u> , Vol. 42; pp. 461-489, (2003).
	CJJ	Truong, Daniel D., et al., "BotB (Botulinum Toxin Type B): Evaluation of Safety and Tolerability in Botulinum Toxin Type A-Resistant Cervical Dystonia Patients" <u>Movement Disorders</u> , Vol. 12, No. 5; pp. 772-775, (September 1997).
	CKK	Tsui, J.K., et al., "A Pilot Study on the Use of Botulinum Toxin in Spasmodic Torticollis" <u>Can. J. Neurol. Sci.</u> , Vol. 13, No. 4; pp. 314-316, (1985).
	CLL	Tsui, Joseph K.C., et al., "Local Treatment Spasmodic Torticollis with Botulinum Toxin" <u>Le Journal Canadien des Sciences Neurologiques</u> , Vol. 14, No. 3; pp. 533-535, (August 1987).
	CMM	Wainwright, R.B., et al., "Food-Borne Botulism in Alaska, 1947-1985: Epidemiology and Clinical Findings" <u>J. Infect. Dis.</u> , Vol. 157, No. 6; pp. 1158-1162, (1988).
	CNN	Wohlfarth, et al., "Pharmacokinetic Properties of Different Formulations of Botulinum Neurotoxin Type A" <u>Naunyn Schmiedeberg's Arch. Pharmacol.</u> , Vol. 365 (Supp 2), R48, (2002).

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